



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/502,664	02/11/2000	Ronald D. Vale	REGEN1500-1	5502

7590

04/22/2003

Lisa A Haile  
Gary Cary Ware & Freidenrich LLP  
4365 Executive Drive  
Suite 1100  
San Diego, CA 92121-2133

EXAMINER

ROBINSON, HOPE A

ART UNIT

PAPER NUMBER

1653

DATE MAILED: 04/22/2003

23

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
09/502,664

Applicant(s)  
Vale et al.

Examiner  
HOPE ROBINSON

Art Unit  
1653



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on May 7, 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1, 3-12, and 104-111 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 4-7, and 9-12 is/are rejected.
- 7) ☒ Claim(s) 3, 8, and 104-111 is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 18
- 4) ☒ Interview Summary (PTO-413) Paper No(s). 24
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Art Unit: 1653

### **DETAILED ACTION**

1. Applicant's response to the Office Action mailed July 30, 2002 in Paper No. 21 on January 29, 2003 is acknowledged.
2. Claims 105-111 have been added. Claim 8 has been amended. Claims 1, 3-12 and 104-111 are pending and under examination.
3. The following rejections are or remain applicable:

### ***Claim Objections***

4. Claim 1 recites "comprising;" instead of "comprising:"  
Claim 3 depends from claims 1 and 2, and claim 2 is canceled.  
Claims 8 and 107 have the recitation of "polystyrene" three times. See also "coverslips" which should be "cover slips" and "polyacrylimide" which should be polyacrylamide.  
Claim 9 is objected to because the claim does not have a period (.).  
Claim 106 recites "...by acylation with an amino acid,.", delete comma.

Art Unit: 1653

***Claim Rejections - 35 U.S.C. § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 4-7 and 9-12 remain rejected under 35 U.S.C. 102(a) as being anticipated by Tsien et al. (U.S. Patent No. 6,008,378, December 28, 1999).

Tsien teach biarsenical molecules and target sequence (FlAsH) see Figure 3. Tsien teaches that the biarsenical molecule preferably is capable of traversing a biological membrane, and includes a detectable group, for example, fluorescent group, luminescent group, phosphorescent group, spin label, photosensitizer, photocleavable moiety, chelating center, heavy atom, radioactive isotope, isotope detectable by nuclear magnetic resonance, paramagnetic atom and combinations thereof (see specification page 4 where the modified FlAsH is defined and claim 1 of the present application). Tsien also teach examples of these groups in Figures 6, 8 and 9 which demonstrates a modified FlAsH (see claim 1). Tsien further teaches that the biarsenical molecule is bonded to a dithiol such as EDT (see claims 9 and 10) and may be coupled to a solid

Art Unit: 1653

phase (see claim 1). In addition, Tsien teaches that the target sequence may be modified by the addition of the motif Cys-Cys-X-Y-Cys-Cys, wherein X and Y are amino acids (the same or different amino acids as in claims 4-7 of the application). The reference teaches that cysteines are positioned for encouraging arsenic interaction across helical turns. Finally, Tsien teaches a polypeptide in solution obtained from cells (from a eukaryote or prokaryote ) and that the polypeptide is isolated with the use of FlAsH (see abstract, columns 1-8, claims 10-12 and Example 2 of the reference). Thus, the teachings of the reference anticipates the present claims.

6. Claims 1, 4-7 and 9-12 remain rejected under 35 U.S.C. 102(b) as being anticipated by Griffin et al. (Science, vol. 281, pages 269-272, July 10, 1998).

Griffin teach the compound known as FlAsH and that it specifically interacts with proteins tagged with a Cys-Cys-X-X-Cys-Cys containing helix (see claim 1, 4-7). Griffin also teach that the dithiols EDT is used called FLASH-EDT to facilitate purification of the protein (see claims 9-10). Griffin also teaches a method of protein isolation that involves the polypeptide in solution from a eukaryote or prokaryote (claims 11 and 12). As Griffin teaches a method of protein isolation that uses the compound FlAsH in a modified form as claimed, the reference anticipates the claimed invention (see abstract and pages 269-272 of the reference).

Art Unit: 1653

7. Applicant's amendment filed January 29, 2003 has been considered and the rejection under 35 U.S.C. 112, second paragraph has been withdrawn. Note however, that the art rejections of record remain. The response on page 4+ argues that claim 1 is definite with regard to "solid support", as the rejection has been withdrawn this issue is moot. It is noted that applicant submitted a new claim 107 which reflects the changes suggested for claim 1. It is suggested that applicant cancel claim 1 in view of claim 107 as the claim broadly reads "solid support".

Regarding the art rejections, applicant on pages 7-8 state that the cited patent '378 and reference by Griffen et al. do not teach a modified FlAsh compound which is modified by acylation with an amino acid. It is noted that the references of record do not teach acylation via an amino acid, however, the references teach acylation via an anhydride, tautomer or salt (see for example, column 3 of U.S. Patent No. 6,008,378, line 35, where it is stated that "the tautomers, anhydrides and salts of the biarsenical molecule of formula III are also included. Thus, the reference does not say to acylate because the compound taught by the reference has already been modified by acylation with an anhydride, salt or tautomer as required by claim 1 of the instant application. The claim as written is in the alternative. If the claim is amended to recite acylation with an amino acid and the anhydride, tautomer and salt are deleted then the rejection of record will be withdrawn. Therefore, applicant's assertion in the response not accurate as both references, Griffen et al. and Tsien et al. ('378) teach that the FlAsh compound comprises anhydrides, tautomers and salt which are methods of acylation.. Claim 1 recites "...modified by

Art Unit: 1653

acylation with an amino acid, or a tautomer, anhydride or salt...”, thus the claim as written, with the alternative, acylation via anhydrides, tautomers etc. as disclosed by the references anticipates the claimed invention. Therefore, the rejection remains.

### ***Conclusion***

8. Applicant’s amendment necessitated the new/modified ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

9. No claims are allowable.

Art Unit: 1653

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Hope A. Robinson whose telephone number is (703)308-6231. The Examiner can normally be reached on Monday - Friday from 9:00 A.M. to 5:30 P.M. (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor Christopher S.F. Low, can be reached at (703)308-2932.

Any inquiries of a general nature relating to this application should be directed to the Group Receptionist whose telephone number is (703)308-0196.

Papers related to this application may be submitted by facsimile transmission. The official fax phone number for Technology Center 1600 is (703) 308-2742. Please affix the Examiner's name on a cover sheet attached to your communication should you choose to fax your response. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989).

Hope A. Robinson, MSAR

Patent Examiner

Christopher S. F. Low  
CHRISTOPHER S. F. LOW  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600